

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 3285
OFFERED BY M . _____**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the “Fairness for Patient
3 Medications Act”.

**4 SEC. 2. REQUIREMENTS WITH RESPECT TO COST-SHARING
5 FOR HIGHLY REBATED DRUGS.**

6 (a) PHSA.—Part D of title XXVII of the Public
7 Health Service Act (42 U.S.C. 300gg–111 et seq.) is
8 amended by adding at the end the following:

**9 “SEC. 2799A–11. REQUIREMENTS WITH RESPECT TO COST-
10 SHARING FOR HIGHLY REBATED DRUGS.**

11 “(a) IN GENERAL.—No later than December 31,
12 2025, and annually thereafter, the Secretary shall—

13 “(1) aggregate the data from the reports sub-
14 mitted under section 2799A–10, section 725 of the
15 Employee Retirement Income Security Act, and sec-
16 tion 9825 of the Internal Revenue Code of 1986, to
17 determine the total spending and rebates, reductions
18 in price, or other remuneration for each drug for

1 which data is available, in the most recent calendar
2 year for which such information is available; and

3 “(2) certify (or recertify, if applicable) and pub-
4 licly list as a ‘highly rebated drug’ any drug identi-
5 fied in such reports for which total rebates, reduc-
6 tions in price, or other remuneration in the calendar
7 year aggregated across all reports submitted pursu-
8 ant to such sections exceeded 50 percent of total an-
9 nual spending reported by group health plans and
10 health insurance issuers offering group or individual
11 health coverage on such drug in such year.

12 “(b) DEDUCTIBLE AND COST-SHARING LIMITATIONS
13 FOR CERTIFIED DRUGS.—For plan years that begin on
14 or after January 1, 2027, a group health plan or a health
15 insurance issuer offering group or individual health insur-
16 ance coverage (or entity that provides pharmacy benefits
17 management services on behalf of such a plan or issuer)
18 that provides coverage of any highly rebated drug shall
19 not impose cost-sharing in excess of, the average net price
20 paid by such group health plan or health insurance issuer
21 (or entity that provides pharmacy benefits management
22 services on behalf of such a plan or issuer), in the most
23 recent calendar year for which a final net price has been
24 calculated by such plan or coverage (or entity that pro-

1 vides pharmacy benefit management services on behalf of
2 such plan or issuer), for the equivalent quantity.

3 “(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT
4 TO FORMULARY EXCLUSION.—Beginning on January 1,
5 2027, in the case of a specific highly rebated drug covered
6 by a group health plan or health insurance issuer offering
7 group or individual health insurance coverage (or entity
8 that provides pharmacy benefits management services on
9 behalf of such plan or issuer) that provides coverage of
10 a specific highly rebated drug that was not covered in a
11 previous year or has no net price calculated under sub-
12 section (a), such group health plan or health insurance
13 issuer (or entity that provides pharmacy benefit manage-
14 ment services on behalf of such plan or issuer) shall not
15 receive from a drug manufacturer a rebate, reduction in
16 price or other remuneration with respect to such specific
17 highly rebated drug received by an enrollee in the plan
18 or coverage and covered by the plan or coverage, unless—

19 “(1) any such reduction in price is reflected at
20 the point of sale to the enrollee; and

21 “(2) any such other remuneration is a flat fee-
22 based service fee not contingent on total volume of
23 sales that a manufacturer of prescription drugs pays
24 to an entity that provides pharmacy benefits man-
25 agement services.

1 “(d) DEFINITIONS.—In this section:

2 “(1) ENTITY THAT PROVIDES PHARMACY BENE-
3 FITS MANAGEMENT SERVICES.—The term ‘entity
4 that provides pharmacy benefits management serv-
5 ices’ means—

6 “(A) any entity that, pursuant to a written
7 agreement with a group health plan or a health
8 insurance issuer offering group or individual
9 health insurance coverage, directly or through
10 an intermediary—

11 “(i) acts as a price negotiator on be-
12 half of the plan or coverage; or

13 “(ii) manages the prescription drug
14 benefits provided by the plan or coverage,
15 which may include the processing and pay-
16 ment of claims for prescription drugs, the
17 performance of drug utilization review, the
18 processing of drug prior authorization re-
19 quests, the adjudication of appeals or
20 grievances related to the prescription drug
21 benefit, contracting with network phar-
22 macies, controlling the cost of covered pre-
23 scription drugs, or the provision of related
24 services; or

1 “(B) any entity that is owned, affiliated, or
2 related under a common ownership structure
3 with an entity described in subparagraph (A).

4 “(2) NET PRICE.—The term ‘net price’, with
5 respect to a prescription drug, means the final price
6 paid by a group health plan or health insurance
7 issuer offering group or individual health insurance
8 coverage (or entity that provides pharmacy benefits
9 management services on behalf of such a plan or
10 issuer) after applying all rebates (including rebates
11 retained by any entity that provides pharmacy bene-
12 fits management services on behalf of such a plan or
13 issuer), reductions in price, and other remuneration
14 under the plan or coverage from drug manufacturers
15 during the plan year.

16 “(e) SPECIFICATION.—A health insurance plan will
17 not fail to be treated as an HDHP for complying with
18 the cost-sharing cap in this section.”.

19 (b) ERISA.—

20 (1) IN GENERAL.—Subpart B of part 7 of sub-
21 title B of title I of the Employee Retirement Income
22 Security Act of 1974 (29 U.S.C. 1185 et seq.) is
23 amended by adding at the end the following:

1 **“SEC. 725. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
2 **ING FOR HIGHLY REBATED DRUGS.**

3 “(a) IN GENERAL.—No later than December 31,
4 2025, and annually thereafter, the Secretary shall—

5 “(1) aggregate the data from the reports sub-
6 mitted under section 725, section 2799A–10 of the
7 Public Health Service Act, and section 9825 of the
8 Internal Revenue Code of 1986, to determine the
9 total spending and rebates, reductions in price, or
10 other remuneration for each drug for which data is
11 available, in the most recent calendar year for which
12 such information is available; and

13 “(2) certify (or recertify, if applicable) and pub-
14 licly list as a ‘highly rebated drug’ any drug identi-
15 fied in such reports for which total rebates, reduc-
16 tions in price, or other remuneration in the calendar
17 year aggregated across all reports submitted pursu-
18 ant to such sections exceeded 50 percent of total an-
19 nual spending reported by group health plans and
20 health insurance issuers offering group health cov-
21 erage on such drug in such year.

22 “(b) DEDUCTIBLE AND COST-SHARING LIMITATIONS
23 FOR CERTIFIED DRUGS.—For plan years that begin on
24 or after January 1, 2027, a group health plan or a health
25 insurance issuer offering group health insurance coverage
26 (or entity that provides pharmacy benefits management

1 services on behalf of such a plan or issuer) that provides
2 coverage of any highly rebated drug shall not impose cost-
3 sharing in excess of, the average net price paid by such
4 group health plan or health insurance issuer (or entity
5 that provides pharmacy benefits management services on
6 behalf of such a plan or issuer), in the most recent cal-
7 endar year for which a final net price has been calculated
8 by such plan or coverage (or entity that provides pharmacy
9 benefit management services on behalf of such plan or
10 issuer), for the equivalent quantity of such specific highly
11 rebated drug.

12 “(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT
13 TO FORMULARY EXCLUSION.—Beginning on January 1,
14 2027, in the case of a specific highly rebated drug covered
15 by a group health plan or health insurance issuer offering
16 group health insurance coverage (or entity that provides
17 pharmacy benefits management services on behalf of such
18 plan or issuer) that provides coverage of a specific highly
19 rebated drug that was not covered in a previous year or
20 has no net price calculated under subsection (a), such
21 group health plan or health insurance issuer (or entity
22 that provides pharmacy benefit management services on
23 behalf of such plan or issuer) shall not receive from a drug
24 manufacturer a rebate, reduction in price or other remu-
25 nation with respect to such specific highly rebated drug

1 received by an enrollee in the plan or coverage and covered
2 by the plan or coverage, unless—

3 “(1) any such reduction in price is reflected at
4 the point of sale to the enrollee; and

5 “(2) any such other remuneration is a flat fee-
6 based service fee not contingent on total volume of
7 sales that a manufacturer of prescription drugs pays
8 to an entity that provides pharmacy benefits man-
9 agement services.

10 “(d) DEFINITIONS.—In this section:

11 “(1) ENTITY THAT PROVIDES PHARMACY BENE-
12 FITS MANAGEMENT SERVICES.—The term ‘entity
13 that provides pharmacy benefits management serv-
14 ices’ means—

15 “(A) any entity that, pursuant to a written
16 agreement with a group health plan or a health
17 insurance issuer offering group health insur-
18 ance coverage, directly or through an inter-
19 mediary—

20 “(i) acts as a price negotiator on be-
21 half of the plan or coverage; or

22 “(ii) manages the prescription drug
23 benefits provided by the plan or coverage,
24 which may include the processing and pay-
25 ment of claims for prescription drugs, the

1 performance of drug utilization review, the
2 processing of drug prior authorization re-
3 quests, the adjudication of appeals or
4 grievances related to the prescription drug
5 benefit, contracting with network phar-
6 macies, controlling the cost of covered pre-
7 scription drugs, or the provision of related
8 services; or

9 “(B) any entity that is owned, affiliated, or
10 related under a common ownership structure
11 with an entity described in subparagraph (A).

12 “(2) NET PRICE.—The term ‘net price’, with
13 respect to a prescription drug, means the final price
14 paid by a group health plan or health insurance
15 issuer offering group health insurance coverage (or
16 entity that provides pharmacy benefits management
17 services on behalf of such a plan or issuer) after ap-
18 plying all rebates (including rebates retained by any
19 entity that provides pharmacy benefits management
20 services on behalf of such a plan or issuer), reduc-
21 tions in price, and other remuneration under the
22 plan or coverage from drug manufacturers during
23 the plan year.

1 “(e) SPECIFICATION.—A health insurance plan will
2 not fail to be treated as an HDHP for complying with
3 the cost-sharing cap in this section.”.

4 (2) CLERICAL AMENMDNET.—The table of con-
5 tents in section 1 of the Employee Retirement In-
6 come Security Act of 1974 (29 U.S.C. 1001 et seq.)
7 is amended by inserting after the item related to
8 section 725 the following:

“Sec. 726. Requirements with respect to cost-sharing for highly rebated
drugs.”.

9 (c) IRC.—

10 (1) IN GENERAL.—Subchapter B of chapter
11 100 of the Internal Revenue Code of 1986 is amend-
12 ed by adding at the end the following new section:

13 **“SEC. 9826. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
14 **ING FOR HIGHLY REBATED DRUGS.**

15 “(a) IN GENERAL.—No later than December 31,
16 2025, and annually thereafter, the Secretary shall—

17 “(1) aggregate the data from the reports sub-
18 mitted under section 9825, section 2799A–10 of the
19 Public Health Service Act, and section 725 of the
20 Employee Retirement Income Security Act, to deter-
21 mine the total spending and rebates, reductions in
22 price, or other remuneration for each drug for which
23 data is available, in the most recent calendar year
24 for which such information is available; and

1 “(2) certify (or recertify, if applicable) and pub-
2 licly list as a ‘highly rebated drug’ any drug identi-
3 fied in such reports for which total rebates, reduc-
4 tions in price, or other remuneration in the calendar
5 year aggregated across all reports submitted pursu-
6 ant to such sections exceeded 50 percent of total an-
7 nual spending reported by group health plans on
8 such drug in such year.

9 “(b) DEDUCTIBLE AND COST-SHARING LIMITATIONS
10 FOR CERTIFIED DRUGS.—For plan years that begin on
11 or after January 1, 2027, a group health plan (or entity
12 that provides pharmacy benefits management services on
13 behalf of such a plan) that provides coverage of any highly
14 rebated drug shall not impose cost-sharing in excess of,
15 the average net price paid by such group health plan (or
16 entity that provides pharmacy benefits management serv-
17 ices on behalf of such a plan), in the most recent calendar
18 year for which a final net price has been calculated by
19 such plan (or entity that provides pharmacy benefit man-
20 agement services on behalf of such plan), for the equiva-
21 lent quantity.

22 “(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT
23 TO FORMULARY EXCLUSION.—Beginning on January 1,
24 2027, in the case of a specific highly rebated drug covered
25 by a group health plan (or entity that provides pharmacy

1 benefits management services on behalf of such plan) that
2 provides coverage of a specific highly rebated drug that
3 was not covered in a previous year or has no net price
4 calculated under subsection (a), such group health plan
5 (or entity that provides pharmacy benefit management
6 services on behalf of such plan) shall not receive from a
7 drug manufacturer a reduction in price or other remunera-
8 tion with respect to such specific highly rebated drug re-
9 ceived by an enrollee in the plan and covered by the plan,
10 unless—

11 “(1) any such reduction in price is reflected at
12 the point of sale to the enrollee; and

13 “(2) any such other remuneration is a flat fee-
14 based service fee not contingent on total volume of
15 sales that a manufacturer of prescription drugs pays
16 to an entity that provides pharmacy benefits man-
17 agement services.

18 “(d) DEFINITIONS.—In this section:

19 “(1) ENTITY THAT PROVIDES PHARMACY BENE-
20 FITS MANAGEMENT SERVICES.—The term ‘entity
21 that provides pharmacy benefits management serv-
22 ices’ means—

23 “(A) any entity that, pursuant to a written
24 agreement with a group health plan, directly or
25 through an intermediary—

1 “(i) acts as a price negotiator on be-
2 half of the plan; or

3 “(ii) manages the prescription drug
4 benefits provided by the plan, which may
5 include the processing and payment of
6 claims for prescription drugs, the perform-
7 ance of drug utilization review, the proc-
8 essing of drug prior authorization requests,
9 the adjudication of appeals or grievances
10 related to the prescription drug benefit,
11 contracting with network pharmacies, con-
12 trolling the cost of covered prescription
13 drugs, or the provision of related services;
14 or

15 “(B) any entity that is owned, affiliated, or
16 related under a common ownership structure
17 with an entity described in subparagraph (A).

18 “(2) NET PRICE.—The term ‘net price’, with
19 respect to a prescription drug, means the final price
20 paid by a group health plan (or entity that provides
21 pharmacy benefits management services on behalf of
22 such a plan) after applying all rebates (including re-
23 bates retained by any entity that provides pharmacy
24 benefits management services on behalf of such a
25 plan), reductions in price, and other remuneration

1 under the plan from drug manufacturers during the
2 plan year.

3 “(e) SPECIFICATION.—A health insurance plan will
4 not fail to be treated as an HDHP for complying with
5 the cost-sharing cap in this section.”.

6 (2) CLERICAL AMENDMENT.—The table of sec-
7 tions for subchapter B of chapter 100 of such Code
8 is amended by adding at the end the following new
9 item:

“Sec. 9826. Requirements with respect to cost-sharing for highly rebated
drugs.”.

10 **SEC. 3. PBM REPORTING AND INCREASED FLEXIBILITY.**

11 (a) PHSA.—Section 2799A–10(a) of the Public
12 Health Service Act (42 U.S.C. 300gg–111(a)) is amend-
13 ed—

14 (1) in the matter preceding paragraph (1), by
15 striking “, a group health plan or health insurance
16 issuer offering group or individual health insurance
17 coverage (except for a church plan)” and inserting
18 “(or at such time as specified by the Secretary), a
19 group health plan or health insurance issuer offering
20 group or individual health insurance coverage (ex-
21 cept for a church plan), or an entity providing phar-
22 macy benefits management services on behalf of
23 such plan or coverage,”; and

1 (2) in paragraph (9)(B), by inserting “by the
2 plan or coverage, and by the patient,” after “the
3 amounts so paid”.

4 (b) ERISA.—Section 725(a) of the Employee Retirement
5 Income Security Act (29 U.S.C. 1195n(a)) is amended—
6 ed—

7 (1) in the matter preceding paragraph (1), by
8 striking “, a group health plan (or health insurance
9 coverage offered in connection with such a plan)”
10 and inserting “(or at such time as specified by the
11 Secretary), a group health plan (or health insurance
12 coverage offered in connection with such a plan), or
13 an entity providing pharmacy benefits management
14 services on behalf of such plan or coverage,”; and

15 (2) in paragraph (9)(B), by inserting “by the
16 plan or coverage, and by the patient,” after “the
17 amounts so paid”.

18 (c) IRC.—Section 9825(a) of the Internal Revenue
19 Code of 1986 is amended—

20 (1) in the matter preceding paragraph (1), by
21 striking “, a group health plan” and inserting “(or
22 at such time as specified by the Secretary), a group
23 health plan, or an entity providing pharmacy bene-
24 fits management services on behalf of such plan,”;
25 and

1 (2) in paragraph (9)(B), by inserting “by the
2 plan or coverage, and by the patient,” after “the
3 amounts so paid”.

